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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,945	01/07/2002	Graham C Crawley	P 0284166	8745

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT PAPER NUMBER

1624

DATE MAILED: 12/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,945

Applicant(s)

CRAWLEY ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 3-5, 10-13, 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 14 is/are rejected.
- 7) ☒ Claim(s) 6-9 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other: _____

DETAILED ACTION

Lack of Unity

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- ❑ **Group I**, claim(s) 1, 2 (in part), 6-9, and 14 (in part), drawn to compounds and composition of formulae Ia, and II; classified in class 544, subclasses 284-289, 291-293.
- ❑ **Group II**, claim(s) 1 (in part), 4, 10-12, and 14 (in part), drawn to compounds and composition of formulae Ic, and IV; classified in class 544, subclasses 254-258, 262-264, 270, 278-280.
- ❑ **Group III**, claim(s) 1 (in part), 5, and 14 (in part), drawn to compounds and composition of formulae Id, and V; classified in class 544, subclasses 249-251.
- ❑ **Group IV**, claims 1, 3, and 14, drawn to compounds, and composition of formulae Ib and III; classified in class 546, subclasses 134, 135.
- ❑ **Group V**, claim(s) 13, drawn to multiple processes; classified in classes 544, and 546, various subclasses depending on its substituents.
- ❑ **Group VI**, claim(s) 15, and 16, drawn to the use or method of prevention or treatment of T-cell mediated diseases using compounds of formula I; classified in class 514, various subclasses depending on substituents. Further restriction will be required if this group is elected.

The inventions of Groups I, II, III, and VI are unrelated because they do not share the same

or corresponding technical feature. The compounds in each group have a different ring system, which is patentably distinct over each other. The common functional group $-N-C(=Z)-N$ alone does not define the invention since such a group is known, and is not applicant's contribution to the art. Thus, it is the combination of said functional group and a ring represented by Ia, Ib, Ic, or Id that gives the compounds of each group the novel physical and chemical properties.

Therefore, a reference read on one group would not do so to the other groups. Thus, a separate search is required for each group, which poses a burden of searching.

The invention of Group IV is drawn to multiple processes of making compounds of formula I. According to PCT rule, applicant is entitled to one process. The invention of Group V is drawn to method of use and/or treatment, which had different patentability criteria. That is, a reference anticipated a compound would not anticipate the method of use and/or treatment using the same compound.

The examiner has required restriction between compounds and process or method claims. Where applicant elects claims directed to the compound, and a compound claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable compound claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process or method claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted

after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the compound claims and the rejoined process or method claims will be withdrawn, and the rejoined process or method claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between compound claims and process or method claims may be maintained. Withdrawn process or method claims that are not commensurate in scope with an allowed method claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process or method claims should be amended during prosecution either to maintain dependency on the compound claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

A faxed response from Mr. Donald Bird on 6-16-03 indicated that a provisional election was made without traverse to prosecute the invention of Group I, claims 1, 2, 6-9, and 14.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 3-5, 10-13, 15 and 16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. **Lack of Written Description (New Matter):** Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The proviso in claim 1 includes

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a species (on the last line) which has no description in the specification. Note, even a **negative limitation requires description**, *Ex Parte Grasselli*, 231 USPQ 393.

2. **Scope of Enablement:** Claims 1, 2, and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being **enabling for** the preparation of compounds of formula Ia or II wherein Q² is an aryl, aryl-(1-3C)alkyl, or aryl-(3-7C)cycloalkyl group, does **not** reasonably provide **enablement for** the preparation of compounds of formula Ia or II wherein Q² is a **heteroaryl, heteroaryl-(1-3C)alkyl, or heteroaryl-(3-7C)cycloalkyl group**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

- (1) The breadth of the claims;
- (2) The amount of direction or guidance presented;
- (3) The state of the prior art;
- (4) The relative skill of those in the art;
- (5) The predictability or unpredictability of the art;
- (6) The quantity of experimentation necessary;

[See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

- a. **The breadth of the claims:** Claims 1 and 2 encompass a plethora of compounds in which Q^2 can be any ring ranging from a phenyl group to a complicated bicyclic heteroaryl system of various combination of heteroatoms. It is rather unpredictable for the structure of formula (I) when Q^2 as a heteroaryl group or heteroaryl-containing group.
- b. **The amount of direction or guidance presented:** Although the specification provides many intermediate formulae having Q^2 , it does not appear to teach how those formulae can be obtained. All working examples are drawn to compounds having Q^2 as a phenyl, benzyl or phenylethyl group. Thus, following the working examples, one can only obtain compounds having Q^2 as a phenyl, benzyl, or phenylethyl group. Furthermore, it appears that only compounds with Q^2 as phenyl, benzyl or phenylethyl are tested for the inhibitions of p56^{lck}, T-cell activation, cytokine production, and transplant rejection. Because of the structural difference between phenyl, and heteroaryl groups, the biological activities of the tested compounds cannot be extrapolated to compounds with Q^2 as a heteroaryl group, or heteroaryl-containing group.
- c. **The state of the prior art,** as evident by Chan et. al. (WO 99/09024), does not disclose species having the combination of quinazoline with urea with another heteroaryl group, nor does it link such a combination to the activity of T-cell, cytokine production, or transplant rejection, etc. Without an established correlation, one skilled in the art would have to carry out extensive research to make and use the claimed compounds of formula I with Q^2 as a heteroaryl group, or heteroaryl-containing group.

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Thus, with **the unpredictable nature of the art**, and limited teaching provided, the skilled chemist would have to carry out undue experimentation to make a compound of formula Ia or II with Q² as a heteroaryl group or a heteroaryl-containing group because the specification fails to describe the structural arrangement for such a compound, and there is no established relationship of those compounds with the inhibition of T-cell activation, cytokine production, or transplant rejection.

Claim Objections

3. Claims 6-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Said claims are drawn to a narrower subgenera and species that are not taught or suggested by the prior arts of record.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 06-10-02 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. It is also acknowledged that the listed references are those cited in the International Search Report.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthorn N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (7 am -12 pm, and 3 pm - 6 pm) starting from 10-1st -03.

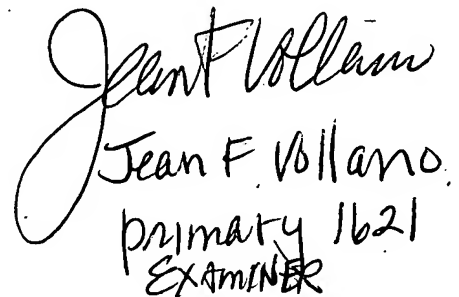
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



T. Truong

December 8, 2003



Jean F. Vellano
primary 1621
EXAMINER